MAR 1 6 2001 K003995

VII. Summary of Safety and Effectiveness statement.

Product Description

OralLite is a non-toxic chemiluminescent illumination source that requires prior chemical activation by the bending of its flexible plastic capsule. The activated OralLite is placed into the provided OralLite holder to facilitate examination of the oral cavity.

INTENDED USE of OralView:

The OralLite is to be used during examination of the oral mucosa in a procedure known as OralView. For optimal results, OralView should be completed within 15 minutes of capsule activation.

OralLite is intended to be used in combination with traditional oral examination by incandescent light by a health care provider to increase identification, evaluation, and monitoring of oral mucosal abnormalities in populations at increased risk for oral cancer.

OralView PROCEDURE:

The OralView procedure with OralLite enables the practitioner to visualize leukoplakic areas of the oral cavity using a diffuse chemiluminescent light source. Under OralLite, atypical or dysplastic mucosal abnormalities will appear as bright white, distinctly demarcated, sharply marginated areas that contrast the surrounding non involved epithelium. Following conventional oral examination with incandescent light, the subject rinses the mouth with acetic acid, the practitioner then activates the OralLite, places it into the OralLite holder, dims the ambient light, and re-examines the oral cavity with OralLite.

PRINCIPLE OF ACTION:

Traditionally, acetowhite or leukoplakic lesions, following application of a cytoplasmic dehydration agent such as an acetic acid solution, have been seen with changes in refractile properties that occur in atypical nonkeratinized squamous epithelium due to an increased nuclear:cytoplasmic ratio.

Supplementing conventional projected incandescent illumination (conventional light) with diffuse chemiluminescent light (OralLite / Speculite) has been clinically shown to increase the detection of biopsy proven squamous cell dysplasia and malignancy in squamous epithelium in the lower female genital tract when compared with both detection by the naked eye and detection with magnified visualization with incandescent light.

ADVERSE EVENTS

None Known.

CLINICAL STUDIES

In Clinical use, in patients at increased risk for oral cancer, the OralView exam (using OralLite) improves the ability to identify, evaluate, and monitor lesions which on biopsy may include cancer and neoplasia.

CONTRAINDICATIONS:

OralView should not be used without prior conventional oral examination with incandescent light.

WARNINGS/PRECAUTIONS

To prevent swallowing or choking:

The health care provider should ensure that the activated OralLite® is **firmly inserted** into the provided OralLite holder before placing it into the patient's mouth.

The health care provider should hold firmly onto the OralLite holder while it is placed inside the patient's mouth.

To prevent potential leakage of OralLite chemicals into the mouth:

Inspect the OralLite for any evidence of chemical leakage prior to capsule activation. Discard any capsule that does not appear to be intact.

Inspect the activated OralLite for potential leakage before placing it into the patient's mouth for OralView.

Do not use a capsule for OralView if the capsule does not appear to be intact or functioning properly.

Oral exposure to the contents of the OralLite lightstick may cause transient irritation to the mouth, throat and gastrointestinal tract.

[**Note**: The chemiluminescent chemicals and the materials used in the manufacturer of the OralLite have been shown to be non-toxic in animal studies should they be either swallowed or applied to the epithelial surface. Therefore, the OralLite and the chemiluminescent chemicals should not present a significant risk to humans when used as a light source for oral examination under usual conditions.]

[**Note**: Remedy for accidental exposure to chemicals: Rinse mouth immediately and dilute with 4 to 8 ounces of milk or water. Decontamination with syrup of ipecac,

activated charcoal or gastric lavage is not indicated.]

After 15 minutes the chemiluminescent light begins to fade and the ability to visualize white lesions will also decrease. Therefore, perform the examination of oral tissues within 15 minutes of OralLite activation.

OralLite is to be used as an adjunct to conventional oral examination OralLite is not intended to be used for grading acetowhite lesions.

All activated and /or used OralLite® must be discarded in a proper receptacle per the procedures of the facility.

OralLite is intended as a disposable, single patient device.

OralLite is not reusable.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 1 6 2001

Mr. Martin Lonky
President
Trylon Corporation
970 West 190th Street, Suite 850
Torrance, California 90502-1037

Re: K003995
Trade Name: Speculite/Orallite
Regulatory Class: II
Product Code: EAZ
Dated: December 22, 2000
Received: December 26, 200

Dear Mr. Lonky:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does

not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K003995 Page 1 of 1

Device Name: OralLite

Indications For Use:

ORAL/OralView, a diffuse chemiluminescent light source, when used in combination with conventioal visual oral mucosal examination by health care providers, improves identification, evaluation, and monitoring of oral mucosal abnormalities in a patient population at increased risk for oral cancer.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use xx OR Over-The-Counter Use
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

Susan Runner

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K003995